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K953806

Attachment VI: Summary of Safety and Effectiveness Information [510(k) Summary]

SYNTHES (USA)
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Device: Synthes Midfacial System, as compared to the Howmedica Luhr Pan Fixation System.

The Synthes Midfacial System is a plate and screw system, manufactured from commercially pure (CP) titanium, and is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin. The plates are available in a variety of configurations to accommodate various fracture sites, and attach to bone via 1.3 mm or 1.7 mm self-tapping screws, with a low plate/screw profile.

The Howmedica Luhr Pan Fixation System, manufactured from Vitallium® alloy, is also intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin. The plates are also available in a variety of configurations to accommodate various fracture sites, and attach to bone via 1.3 mm or 1.5mm self-tapping screws, with a low plate/screw profile.

Synthes will provide the device non-sterile. Of course, non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended

Based on mechanical test results, the Synthes Midfacial System is equivalent to the Howmedica Luhr Pan Fixation System..